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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,114	08/24/2001	Barry N. Gellman	BSC-128	3367

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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,114	GELLMAN ET AL.	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 24, 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure. It is suggested that the applicant augment the abstract to describe the invention a bit more fully.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet *within the range of 50 to 150 words*. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The disclosure is objected to because of the following informalities:

On page 6 line 28, change "distal tip 4" to—distal tip 115—.

On page 7 line 8, change "needle carrier 17" to—needle carrier 255—.

On page 7 line 24, change "hole 23" to—hole 320—.

Appropriate correction is required.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Correction of the following is required: Applicant should provide antecedent basis for the following terminology used in the claims: "needle carrier channel" [Claim 17].

still lacks antecedent basis!

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite because in a previously recited claim it was stated that the catch *is disposed on* the elongate body member, and in Claim 12 it is stated that the catch is part of an assembly that *is coupled to* the elongate body member.

Claim Objections

4. Claim 7 is objected to because of the following informality: There is an extra period at the end of the sentence (line 2). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,458,609 to Gordon et al.

5. Regarding Claim 1, Gordon discloses a suturing instrument (2) with an elongate body member (32), a needle deployment system (64a & 58a), and a catch (78a). The

needle deployment system (64a & 58a) is at the distal end of the elongate body member (32) and has a forward deploying needle carrier (58a) [see Column 11, line 35 to Column 12, line 9; see Fig. 4A].

6. Regarding Claims 2 and 3, Gordon discloses a suturing instrument, which also has a deployment controller (42). The deployment controller (42) extends along the longitudinal axis of the elongate body member (32) and its distal end is coupled to the needle carrier (58a) [see Fig. 4A; Column 11, lines 42-63]. There is an actuator (124) coupled to the proximal end of the deployment controller (42) [see Fig. 3; Column 12, lines 47-54].

7. Regarding Claim 4, Gordon discloses a suturing instrument which has a deployment controller (42) which is configured to guide the needle carrier (58a) along a proximal curved path segment leading initially away from the elongate body member (32) and then towards the elongate body member (32) [see 4A; Column 12, lines 65-67]. Figures 13-15 show the progression of the needle carrier (58a) initially moving away from member (32) and then towards member (32).

8. Regarding Claims 5 and 6, Gordon discloses a suturing instrument with a second needle carrier (58b) [see Fig. 4A]. His instrument also includes a suture (92a) with an attached needle (88a) [see Fig. 14; Column 12, lines 14-20].

9. Regarding Claims 7 and 8, Gordon discloses a suturing instrument in which the needle inserts into the needle carrier [see Fig. 6]. The catch (78a) is positioned on the elongate body member (32) such that a distal path segment of the needle carrier's

path is intercepted by the catch (78a) [see progression from Fig. 13 to Fig. 14 to Fig. 15].

10. Regarding Claim 9, Gordon discloses a suturing instrument with a flexible drive member (64a) coupling the deployment controller (42) to the needle carrier (58b). [Column 11, lines 58-63] Gordon's drive member (64a) is "preferably made out of stainless steel," and stainless steel is considered to be just as flexible as an alloy of titanium and nickel, the composition of the applicant's drive member.

11. Regarding Claim 13, Gordon discloses a method for placing a suture in tissue, including several steps: The suturing instrument (2) encloses a forward-deploying needle carrier (58a) including a needle (88a). The forward-deploying needle carrier (58a) is movably positioned within a needle carrier channel adjacent to the tissue to be sutured.

The forward-deploying needle carrier (58a) is deployed out of the suturing instrument through a forward end exit port. The device captures the needle (88a) carried by the forward-deploying needle carrier (58a) in a catch (78a) that receives and retains the needle [see progression from Fig. 13 to Fig. 14 to Fig. 15].

12. Regarding Claim 14, Gordon discloses a method in which deploying the forward-deploying needle carrier (58a) out of the suturing instrument through a forward end exit port includes activating a deployment controller (42). The deployment controller has a distal end, which is connected to the needle carrier (58a) and extends along a longitudinal axis of an elongate body member (32) to the distal portion of the elongate body member (32) [see Fig. 4A; Column 11, lines 42-63]. The distal end of

the deployment controller (42) is coupled to the needle carrier (58a) to facilitate movement of the needle carrier (58a) between a retracted position and a deployed position [see progression from Fig. 13 to Fig. 14 to Fig. 15].

13. Regarding Claim 15, Gordon further discloses a suturing instrument in which deploying the forward-directed exit port involves activating an actuator (124) coupled to the proximal end of the deployment controller (42) [see Fig. 3; Column 12, lines 47-54].

14. Regarding Claim 16, Gordon further discloses a method which includes a suturing instrument which has a deployment controller (42) which is configured to guide the needle carrier (58a) along a proximal curved path segment leading initially away from the elongate body member (32) and then towards the elongate body member (32) [see 4A; Column 12, lines 65-67]. Figures 13-15 show the progression of the needle carrier (58a) initially moving away from member (32) and then towards member (32). The forward-deploying needle carrier (58a) is deployed out of the suturing instrument through a forward end exit port.

15. Regarding Claim 17, Gordon further discloses a method including placing a suturing instrument enclosing a second forward-deploying needle carrier (58b) including a needle (88b), in which the second forward-deploying needle carrier (58b) is movably positioned within a needle carrier channel adjacent the tissue to be sutured [see Fig. 4A, Column 11, lines 62-65]. Note: although Figures 11-15 only show one forward-deploying needle carrier, needle, etc...it should be understood that there are

duplicates (reflections) of each of these components in the embodiment, but only one has been shown for the sake of clarity [Column 12, lines 62-65].

16. Regarding Claim 18, Gordon further discloses a method including placing a suturing instrument enclosing a forward-deploying needle carrier (58a) and associating a suture (92a) with the needle (88a) [see Fig. 15; Column 12, lines 14-20].

17. Regarding Claim 19, Gordon further discloses a method including a catch (78a) is such that a distal path segment of the needle carrier's (58a) path is intercepted by the catch (78a) [see progression from Fig. 13 to Fig. 14 to Fig. 15].

18. Claim 11, as best interpreted, is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,048,351 to Gordon et al. Gordon discloses a suturing instrument (300) with an elongate body member (304); a needle deployment system with a forward-deploying needle carrier (344); and a catch (360) disposed on the elongate body member (304) to receive and retain the needle [see Fig. 16]. The needle carrier (344) and needle catch (360) are at a distal tip assembly coupled to the elongate body member (304) such that the distal tip assembly is free to rotate axially about a longitudinal axis with respect to the elongate body member (304) [see Figures 18A 18B; Column 10, lines 7-15; Column 22, lines 15-27].

19. Claim 12, as best interpreted, is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,860,992 to Daniel et al. Daniel discloses a suturing instrument with an elongate body member (172) [see Fig. 26] and a needle

deployment system (184, 176, 180) at the distal end of the elongate body member (172). The needle deployment system has a forward deploying needle carrier (176) and a catch (183, 184) attached to the elongate body member to receive and retain the needle. The needle carrier (176) and the needle catch (183, 184) are part of an assembly at the distal end of the elongate member (172) that is free to deflect about a pivot joint (190) [see Fig. 26; Column 17, lines 14-35].

Claims 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,899,909 to Claren et al.

20. Regarding Claim 20, Claren discloses a method for shortening the pelvic floor, which includes, several steps. The surgeon places the suturing instrument [whole device shown in Fig. 1], which encloses a forward-deploying needle carrier (19) and includes a needle (21) [Column 3, lines 10-22], adjacent to the tissue of the pelvic floor [see Fig. 4]. Then the surgeon deploys the suturing instrument so that the suture (26) is passed through the tissue of the pelvic floor [see Column 3, lines 47-54]. The general area at which the procedure is done, and more specifically, the "soft tissue at one side of the urethra," is taken to be the pelvic floor [lines 51-52]. The included references [Gyneflex™/U.S. Patent No. 6,224,525 B1, and Human Gross Anatomy and Embryology Pelvic Organs and Pelvic Diaphragm] clarify further what the area of the body known as the "pelvic floor."

Claren's method additionally includes tightening the suture (26) so that the pelvic floor buckles and is shortened in length [Column 4, lines 8-15]. The soft tissue

between the urethra and the vaginal wall is part of the pelvic floor [see Fig. 8 & Column 4, lines 1-7 in light of Gyneflex™ reference], and as the tape is pulled through that area, it will laterally pull the pelvic floor, causing it to buckle and shorten.

Regarding Claim 21, Claren further discloses a method including a second deploying of the suturing instrument such that the suture is passed through the tissue of the pelvic floor prior to tightening the suture such that the pelvic floor buckles and is effectively shortened in height [see Fig. 8; Column 4, lines 1-7]. As noted above, the soft tissue around the urethra is part of the pelvic floor [see Fig. 8 & Column 4, lines 1-7 in light of Gyneflex™ reference], and as the tape is pulled through that area, it will laterally pull the pelvic floor, causing it to buckle and shorten.

21. Regarding Claim 22, Claren's instrument has an elongate body member (10) and a needle deployment system (17, 18, & 19), which is disposed at a distal portion of the elongate body member (10). The deployment system (17, 18, & 19) has a forward-deploying needle carrier (19). Also, Claren's instrument has a catch (14) disposed on the elongate body member (10) to receive and retain the needle [see Fig. 16; Column 3, lines 7-12].

22. Regarding Claim 23, Claren discloses a suturing instrument has a deployment controller (15), which has a distal end and extends along a longitudinal axis of the elongate body member (10) to the distal portion of the elongate body member (10). The distal end of the deployment controller (15) is coupled to the needle carrier (19) to facilitate movement of the needle carrier between a retracted position and a

deployed position [see Column 3, lines 61-67]. The retracted position is illustrated well in Fig. 5, while the deployed position is shown well in Fig. 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,458,609 to Gordon et al. Gordon discloses a suturing instrument, according to the claimed invention, including a flexible driver member. However, Gordon's driver member is made out of stainless steel, rather than an alloy of nickel and titanium. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a nickel-titanium alloy for stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,387,221 to Bisgaard

U.S. Patent No. 5,540,705 to Meade et al.

U.S. Patent No. 4,454,823 to Richardson et al.

U.S. Patent No. 5,665,096 to Yoon

U.S. Patent No. 5,759,188 to Yoon

U.S. Patent No. 5,908,428 to Scirica et al.

U.S. Patent No. 5,911,727 to Taylor

U.S. Patent No. 6,117,067 to Gil-Vernet

U.S. Patent No. 6,454,778 B2 to Kortenbach

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP
bcp
February 7, 2003

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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